

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 5970/S22

APPROVAL LETTER

NDA 5-970/s-022

MAY 03 1977

Elkins-Simm, Inc.
Attention: Thelma C.. Hilibrand
2 Esterbrook Lane
Cherry Hill, NJ 08002

Gentlemen:

We acknowledge the receipt on April 4, 1977, of your communication dated March 29, 1973, enclosing printed labeling pursuant to your supplemental new drug application dated July 19, 1976, for Sotradecol (Sodium tetradecyl sulfate).

The supplemental application provides for labeling revision.

We have completed the review of this supplemental application and it is approved. Our letter of September 14, 1972, detailed the conditions relating to the approval of this application.

Sincerely yours,

5/3/77

Philip G. Walters, M.D.
Acting Director
Division of Surgical-Dental
Drug Products
Bureau of Drugs

cc: NWK-DO
NDA 5-970 Orig.

HFD-160

HFL-10

HFD-616

HFD-160/Dr. Pascual/Mr. Monroe

R/D by FKuerer(HFD-160) 4/12/77

R/D by init. by: CMNealey, jr. 4/12/77

LVPascual 4/12/77

PGWalters 4/13/77

F/T 4/29/77:jw

Doc. Room

APPROVAL

4/29/77

5/2/77

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S22

APPROVABLE LETTER

NDA 5-970/S-022

SEP 09 1976

Elkins-Sinn, Inc.
Attention: Thelma C. Hillbrand
2 Esterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

Reference is made to your supplemental new drug applications of July 19, 1976 and July 26, 1976 submitted pursuant to section 505(b) of the Federal, Food, Drug, and Cosmetic Act for Sotradecol (Sodium Tetradecyl Sulfate).

The supplemental applications provide for labeling revision (S-022) and updating information as required by our Federal Register Notice of June 3, 1976.

We have completed the review of these supplemental applications as submitted with draft labeling. However, before the supplements may be approved, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the draft copy. If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

Please submit twelve copies of the printed package insert.

Sincerely yours,

Marion J. Finkel, M.D.
Associate Director
for New Drug Evaluation
Bureau of Drugs

APPROVABLE

cc: NYK-DO
NDA 5970/S-022, S-023
HFD-100/Dr. Finkel
HFD-160
HFL-10
Med. Officer (Walters), Chemist (Monroe), Pharma.
R/D FKuerer (HFD-160) 8/24/76
R/D init. CMNealey, Jr. 8/26/76
MClark, M.D. 8/30/76
CMNealey, Jr. Supervisory CSO
Final typed ld 8/31/76
Doc. Rm. 160

8/31/76

8/31/76

NDA 5-970/S-022

DEC 13 1976

Elkins-Sinn, Inc.
Attention: Thelma C. Hillbrand
2 Esterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

We acknowledge the receipt on September 17, 1976 of your communication dated September 14, 1976 regarding your supplemental new drug application of July 19, 1976 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sotradecol (Sodium Tetradecyl Sulfate).

The supplemental application as amended provides for labeling revision (S-002) to include the additional statement in the Adverse Reaction Section as requested in our letter of September 3, 1976.

We have completed the review of this supplemental application as submitted with draft labeling. However, before the supplement may be approved, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the draft copy. If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

Please submit twelve copies of the printed package insert.

Sincerely yours,

Marion J. Finkel, M.D.
Associate Director
for New Drug Evaluation
Bureau of Drugs

APPROVABLE

cc: HFR-2300
NDA 5-970/S-022
HFD-100/Dr. Finkel
HFL-10
HFD-616
HFD-160
HFD-160/Walters/Monroe
Supervisory CSO/Nealey
R/D FKuerer(HFD-160)
R/D init. CMNealey, Jr. 9/24/76; GMRachanow 9/27/76
MClark, M.D. 9/27/76
Final typed 1d 10/6/76 Doc. Room 160

10/7/76

10/6/76

10/7/76